

**REMARKS**

Claims 1-54 are currently pending. Applicants gratefully acknowledge that claims 1-8 are allowed.

***Offer To Surrender under 37 C.F.R. § 1.178***

The Examiner states that the reissue application was filed without the required offer to surrender the original patent. However, Applicants respectfully state that the Offer to Surrender Declaration was executed on September 7, 2001 and mailed to the Examiner on December 31, 2001 in Response to Notice to File Missing Parts for Reissue Application. Another copy of the Offer to Surrender Declaration is attached hereto.

***Rejection under 35 USC § 112, First Paragraph***

Claims 9-54 were rejected by the Examiner under 35 USC § 112, first paragraph. The Examiner alleges that the Applicants' specification does not teach or disclose the phrase "a composition formulation additive". Applicants respectfully traverse this rejection.

The written description requirement of 35 USC § 112, first paragraph, does not require the description to be in *ipsis verbis* [i.e. "in the same words"] to be sufficient. Martin v. Johnson, 454 F.2d 746, 751 (CCPA, 1972). Furthermore, newly added claim limitations find support through express, implicit, or inherent disclosure. MPEP 2163 I.B (emphasis added). When the specification clearly conveys to those skilled in the art that the applicant has invented the specific subject matter, regardless of *how* it accomplishes it, the essential goal of the description requirement is met. In re Wright, 866 F.2d 422, 424 (CAFC, 1989) (emphasis in original).

In Wright, the Examiner and Board of Patent Appeals and Interferences ("BPA") rejected an application based on a phrase added to the claims as filed in order to distinguish over the prior art. The phrase was not in *ipsis verbis* in the originally filed specification, the Examiner rejected the claims as having no written description support and the BPA affirmed. The Court of Appeals for the Federal Circuit (CAFC), upon reading the specification, agreed that the phrase was not in

*ipsis verbis* in the specification, however, the subject matter that the phrase conveyed was fully supported by the working examples and the teachings of the specification. The CAFC summarily overturned the BPA.

The Applicants' specification provides adequate support for the phrase "a composition formulation additive" through specific recitation of examples [subgenera and species] within the specification and numerous working examples [embodying the genus]. The phrase "a composition formulation additive" enjoys *implicit* support throughout the specification and specifically within the working examples. For example, at col. 2, line 27 the applicants disclose that it has been unexpectedly found that the combined use of riboflavin and/or the riboflavin derivative with proline and/or glutamine according to the present invention synergistically enhances the action to potentiate immune function. The Applicants further disclose at col. 2, line 36 that the combined use of riboflavin and/or a riboflavin derivative and an antibiotic develops a so-called synergism over those achieved by their single use. As a result, such combined use gives an important effect that the amount of the antibiotic to be used is decreased to a significant extent. The Applicants also disclose at col. 2, line 46 that the combined use of riboflavin and/or a riboflavin derivative and a water-soluble polymer or lecithin enhance the infection protective effect of riboflavin and/or the riboflavin derivative. The Applicants further disclose at col. 2, line 54 that the combined use of riboflavin and/or a riboflavin derivative and a vaccine exhibits a so-called synergism over the immunopotentiating and infection protective effects achieved by their single use. Furthermore, examples 2, 4, 5, and 6 demonstrate the effectiveness of the different composition formulation additives.

The Applicants therefore believe that the phrase "a composition formulation additive" has adequate support and, as such, claims 9-54 are distinguishable over US 5,814,632. Therefore, the rejection based on 35 U.S.C. § 112, first paragraph has been overcome and should be withdrawn.

***Double Patenting Rejection***

Claims 11, 21, 31, and 48-54 are rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1 and 2 of US 5,814,632. Applicants respectfully traverse this rejection.

Claim 1 of US 5,814,632 is directed to a method of treating diseases with a composition consisting of riboflavin and/or a riboflavin derivative. Claim 2 of US 5,814,632 is dependent from claim 1 and recites that the composition is administered in an amount of 0.5-500 mg/kg.

Claims 9, 19, 29, and 48 of the instant reissue application have been amended to recite that the composition comprising riboflavin and/or riboflavin derivative includes a composition formulation additive. Support for this amendment is found, for example, at col. 2, line 27, col. 2, line 36, col. 2, line 46, col. 2, line 54 and Examples 2, 4, 5, and 6.

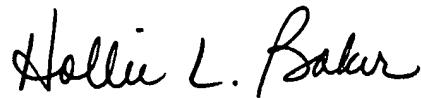
Applicants respectfully submit that claims 11, 21, 31, and 48-54 are not drawn to identical subject matter as claimed in US 5,814,632 and therefore do not give rise to a rejection under 35 U.S.C. § 101. Claims 11, 21, and 31 all are dependent upon independent claims which comprise riboflavin and/or riboflavin derivative and a composition formulation additive. In contrast, claims 1 and 2 of the '632 patent do not recite "a composition formulation additive." Because there is no singular identity of invention, applicants submit that this can not be a proper double patenting rejection. At most, applicants submit that this is potential obviousness-type double patenting between the '632 patent and the rejected claims of the instantly claimed invention.

In view of the foregoing, Applicants feel the rejection is now moot and should be withdrawn.

**CONCLUSION**

Applicants respectfully request reconsideration of the application in light of the remarks made herein. If the examiner believes that a telephonic interview would expedite the allowance of the application, the Examiner is invited to contact the undersigned attorney at the number below.

Respectfully submitted,



Hollie L. Baker  
Registration No. 31,321

Date: July 19, 2004  
Wilmer Cutler Pickering Hale and Dorr LLP  
60 State Street  
Boston, MA 02109  
Telephone: 617-526-6110